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11/18/2003

Ralph Mocikat

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6256

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7590

02/24/2010

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/716,580
Filing Date: November 18, 2003
Appellant(s): MOCIKAT, RALPH

Chuan Gao
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to Appellant's Reply Brief filed 2/3/2010, appealing from the Office action mailed 1/6/2009.

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1. Responsive to the reply brief under 37 CFR 41.41 filed on 2/3/2010, a supplemental Examiner's Answer is set forth below, pursuant to 37 CFR 41.43 and MPEP 1207.05:

Claim Rejections - 35 USC § 112, First Paragraph - Written Description

Claims 1-5, 7-9 and 11-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In the Reply Brief filed 2/3/2010, Appellant replies that "[t]he Examiner's Answer also seems to raise arguments for the written description rejection on new grounds never discussed before" (Reply Brief, page 3, last paragraph through page 4). Appellant argues that "[b]ecause the previous three Office Actions and one Final Office Action have never discussed the question of 'homologous,' Appellant was never put on notice that this question would be of any relevance to the written description assessment. Appellant had therefore made no attempt to address this specific concern during prosecution or even in the Appeal Brief. (Reply Brief, page 4, first full paragraph). Appellant states that because Appellant treats the 'use of the 'homologous' argument in the Examiner's Answer" as a new ground of rejection, "Appellant will therefore not address this particular argument in [the] Reply Brief" (Reply Brief, p. 4, second full paragraph).

Contrary to Appellant's Reply Brief, the written description rejection in the Examiner's Answer did not contain a new rejection or new ground of rejection. The written description rejection was first made in the First Action on the Merits mailed 3/5/2007. On pages 10-11 of that Office Action, the examiner stated that the claims were drawn to genera of vectors encoding genera of nucleic acids homologous to a region comprising the C_μ or C_κ enhancer and that in the absence of sufficient recitation of distinguishing characteristics the specification did not provide adequate written description of the claimed genera. In the Non-Final Office Action mailed 10/18/2007, the rejection was maintained (pp. 3 and 4). In the Non-Final Office Action mailed 4/3/2008, the rejection was maintained (pp. 3-6).

In the 4/3/2008 Office Action, the examiner explained in detail that possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (p. 4). Additionally, the examiner discussed what was known in the prior art and compared what was known in the prior art and in the singular example of the vector in Appellant's specification with the scope of the claimed genera,

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including the genus of nucleic acids homologous to a region comprising the C μ or C κ enhancer (pp 5-6). The examiner explained that neither the specification nor the prior art provided an adequate description of the genus of the claimed vectors encoding “a genus of nucleic acids homologous to a region comprising the C μ or C κ enhancer” (first sentence of page 5). The quoted phrase in the prior sentence was bolded and the word “homologous” was bolded and underlined by the examiner for emphasis (first sentence of page 5). The rejection was again maintained in the Final Office Action, mailed 1/6/2009, and the a genus of nucleic acids homologous to a region comprising the C μ or C κ enhancer remained encompassed in the rejection (pp. 2-6). On page 5 of the Final Rejection, the examiner tried to further clarify the rejection in other terms by explaining that the immunoglobulin κ locus comprises 383,864 base pairs comprises numerous regions, introns, and exons (p. 5). The examiner also noted that the μ locus is similarly situated (p. 5, last sentence). Further, the examiner stated that although the base sequence of the κ locus was known, the skilled artisan would not be readily apprised that Appellant was in possession of a vector comprising an at least 1.5kb segment from one or more of the κ introns (p.6, first paragraph). For the reasons of record and above, Appellant has been afforded an opportunity to respond to the issue of “homology” in the written description rejection and has actually acknowledged the examiner’s arguments related to issues of homology. See Appellant’s Response filed 8/6/2007 at page 11 of 16, paragraphs 2 and 3 and Appellant’s Response filed 1/7/2008, page 7 of 10, last paragraph. The issue of “homology” to an at least 1.5kb segment is and has remained a critical central issue throughout the prosecution of the instant application not only in the written description rejection, but also in the other rejections of record.

MPEP 1207.03(III) states that there is no new ground of rejection when the basic thrust of the rejection remains the same such that an appellant has been given a fair opportunity to react to the rejection. See *In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976). Where the statutory basis for the rejection remains the same, and the evidence relied upon in support of the rejection remains the same, a change in the discussion of, or rationale in support of, the rejection does not necessarily constitute a new ground of rejection. *Id.*

Claim Rejections - 35 USC § 103(a)***Over Mucke, Polack, and Mocikat***

Claims 1-5, 7-9 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polack et al., US Patent 6,521,449 (18 February 2003, benefit to 12 September 1996), Mocikat et al., (Immunology. 1995;84:159-163), and Mucke et al., (Gene Therapy. 1997 Feb;4:82-92).

In the Reply Brief filed 2/3/2010, Appellant replies that “the Examiner has seemingly changed her arguments and now states that the central issue is whether the limitation ‘a continuous region of at least 1.5kb that is homologous to an at least 1.5kb segment of the μ intron or the κ intron’” should be read to cover two κ fragments each less than 1.5kb in length but combinedly [sic] more than 1.5kb” (Reply Brief p. 8, last paragraph). Appellant also argues that the citation of Mocikat would be pertinent only to dependent claim 12 (Reply Brief, p. 8, last paragraph).

In Appellant’s Appeal Brief, filed 9/4/2009, Appellant argues that the primary references “fail to provide at least one limitation of the pending claims, namely ‘a continuous region of at least 1.5kb that is homologous to an at least 1.5kb segment of the μ intron or the κ intron’” (Appeal Brief, p. 10, last paragraph). Appellant also addressed the motivation to combine the teachings of the primary references with Mocikat, which teaches advantageous features of the 2.3kb mouse μ intron (Appeal Brief, p. 10, last paragraph to page 11). In the Examiner’s Answer, mailed 12/4/2009, the examiner answers Appellant’s arguments directed to the primary references as well as the motivation and features of Mocikat’s 2.3kb mouse μ intron (Examiner’s Answer, pages 23-26), which were previously discussed of record.

Appellant may file another reply brief in compliance with 37 CFR 41.41 within two months of the date of mailing of this supplemental examiner’s answer. Extensions of time under 37 CFR 1.136(a) are not applicable to this two month time period. See 37 CFR 41.43(b)-(c).

For the above reasons and the reasons set forth in the Examiner’s Answer, it is believed that the rejections should be sustained.

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A Technology Center Director or designee has approved this Supplemental Examiner's Answer by signing below:

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646

/George C. Elliott, Ph.D./
Director, Technology Center 1600